[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive License: The Development of Diazeniumdiolate Derivatives for Cancer Treatment and Prevention in Humans

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a start-up exclusive patent license to practice the inventions embodied in U.S. Provisional Patent Application No. 60/026,816, entitled "O^2-Aryl Substituted Diazeniumdiolates", filed September 27, 1996, now abandoned (HHS Ref. No. E-093-1996/0-US-01); U.S. Provisional Patent Application No. 60/045,917, entitled "O^2-Aryl Substituted Diazeniumdiolates and Use Thereof", filed May 7, 1997, now abandoned (HHS Ref. No. E-093-1996/1-US-01); U.S. Provisional Patent Application No. 60/051,696, entitled "O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates and O^2-Substituted 1-[(2-Carboxylato) Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates", filed July 3, 1997, now abandoned (HHS Ref. No. E-093-1996/2-US-01); PCT Patent Application No. PCT/US1997/017267, entitled "O^2-Arylated or O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates and O^2-Substituted 1-[(2-Carboxylato) Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates", filed September 26, 1997, now abandoned (HHS Ref. No. E-093-1996/3-PCT-01); European Patent No. 0929538, entitled "O^2-Arylated or O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates and O^2-Substituted 1-[(2-Carboxylato) Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates", issued on November 24, 2004 [HHS Ref. No. E-093-1996/3-EP-02], which is validated in Great Britain [E-093-1996/3-GB-09], Germany [E-093-1996/3-DE-10], France [E-093-1996/3-FR-11], Ireland [E-093-1996/3-IE-12], Italy [E-093-1996/3-IT-13], Switzerland [E-093-1996/3-CH-14] and Belgium [E-

093-1996/3-BE-15]; Australian Patent No. 733590, entitled "O^2-Arylated or O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates and O^2-Substituted 1-[(2-Carboxylato) Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates", issued on August 30, 2001 [HHS Ref. No. E-093-1996/3-AU-03]; Canadian Patent No. 2266908, "O^2-Arylated or O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates and O^2-Substituted 1-[(2-Carboxylato) Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates," issued on July 20, 2010 [HHS Ref. No. E-093-1996/3-CA-04]; Japanese Patent No. 4285775, "O^2-Arylated or O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates and O^2-Substituted 1-[(2-Carboxylato) Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates," issued on April 3, 1999 [HHS Ref. No. E-093-1996/3-JP-05]; U.S. Patent No. 6,610,660, entitled "O^2-Arylated or O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates and O^2-Substituted 1-[(2-Carboxylato) Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates," issued on August 26, 2003 [HHS Ref. No. E-093-1996/3-US-06]; U.S. Patent No. 6,911,433, entitled "O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates," issued on June 28, 2005 [HHS Ref. No. E-093-1996/3-US-07]; European Patent Application No. 04009529.1, entitled "O^2-Arylated or O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates and O^2-Substituted 1-[(2-Carboxylato) Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates," filed on April 22, 2004 [E-093-1996/3-EP-08]; U.S. Patent No. 7,081,524, entitled "O^2-Substituted 1-[(2-Carboxylato)Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates," issued on July 25, 2006 [HHS Ref. No. E-093-1996/3-US-16]; Japanese Patent No. 5015903, entitled "O^2-Substituted 1-[(2-Carboxylato)Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates and Compositions Thereof," issued on June 15, 2012 [HHS Ref. No. E-093-1996/3-JP-17]; Canadian Patent Application No. 2,705,474, entitled "O^2-Glycosylated 1-Substituted Diazen-1-IUM-l,2-Diolates," filed on May 28, 2010 [E-093-1996/3-CA-18]; and European Patent Application No. 10010885.1, entitled "O^2-Substituted 1-[(2-Carboxylato)Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates," filed on September 24, 2012 [E-093-1996/3-EP-19], developed by Dr. Larry K. Keefer, Dr. Joseph E. Saavedra, *et al*. The prospective exclusive license territory may be "worldwide", and the field of use may be limited to: "use of O^2-Arylated, O^2-Glycosylated 1-Substituted Diazen-l-IUM-1,2-Diolates, and O^2-Substituted 1-[(2-Carboxylato) Pyrrolidin-1-YL] Diazen-1-IUM-l,2-Diolates for cancer treatment and prevention in humans." to JSK Therapeutics, Inc. ("JSKT"), a company incorporated under the laws of the State of Delaware having an office in at least Salt Lake City, Utah, U.S.A. The patent rights in these inventions have been assigned to the United States of America.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, patents, inquiries, comments, and other materials relating to the contemplated start-up exclusive license should be directed to: Charlene A. Sydnor, Ph.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4689; Facsimile: (301) 402-0220; E-mail: sydnorc@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications or patents that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This technology concerns a new series of diazeniumdiolate derivatives that are stable in neutral to acidic environments and generate nitric oxide in basic or nucleophilic environments. These synthesized derivatives are potentially suited to the delivery of nitric oxide to basic or nucleophilic compartments within the body. They may be useful for inactivating proteins to prevent detoxification of chemotherapeutic agents or disruption of proteins active in tumor formation, infection, or regulatory activities. The compounds are stable in an aqueous environment but can be activated by enzymatic action to release nitric oxide that is believed to be useful in treating fulminant liver failure, respiratory problems, impotence, and a variety of cardiovascular/hematologic disorders. The diazeniumdiolates have also been derivatized by their incorporation into polymers. These compounds may allow for site specific delivery of nitric oxide. Overall, these compounds appear to be applicable toward the wide variety of processes involving nitric oxide.

The patents and patent applications for this technology contain claims that cover a family of diazeniumdiolate compounds, including: 1) O^2-substituted diazeniumdiolates; 2) O^2-glycosylated diazeniumdiolates; and 3) O^2-substituted 1-[(2-carboxylato)pyrrolidin-1-yl] diazeniumdiolates. Also covered are uses of these compounds as: 1) A treatment for a biological disorder, including angina, acute

myocardial infarction, congestive heart failure, hypertension, and metastasis; 2) A treatment for cancer; and 3) A treatment for an infectious agent, including a virus or parasite.

The prospective start-up exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective start-up exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Properly filed competing applications for a license in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

April 23, 2013
Date

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Richard U. Rodriguez,
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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